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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,369	04/20/2004	Baldomero M. Olivera	2314-278	4193

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/827,369	OLIVERA ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121. This application contains claims directed to patentably distinct methods of use of the following patentably distinct compounds (which have different primary structures) of the claimed invention: the specific peptides of SEQ ID NOS: 2-13. Applicants are required under 35 U.S.C. 121 to elect one method of use of one single disclosed compound for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are limited to one specific peptide. Applicants should note that SEQ ID NO: 1 is 17 amino acids in length and reads on SEQ ID NOS: 3 and 6, but on no others, which are of different lengths. Claim 1 recites that when the disorder is small cell lung carcinoma, the peptide cannot be SEQ ID NO: 2 or 13. But, SEQ ID NO: 1 does not read on these two peptides, which are 16 and 12 amino acids in length, respectively. Thus, the peptide cannot be SEQ ID NO: 2 or 13, no matter which disease treatment method is claimed. The peptide administered is SEQ ID NO: 3 or 6, no matter which disease treatment method is claimed. In the same vein, claim 12 depends from claim 1, but SEQ ID NO: 1 does not read on SEQ ID NOS: 11 and 4, which are 16 amino acids in length. Additionally, claim 16 depends from claim 1, but SEQ ID NO: 1 does not read on SEQ ID NOS: 5, 8, 9 and 12, which are 16 amino acids in length, or on SEQ ID NO: 7, which is 15 amino acids in length. The restriction is as follows.

I. Claims 1-3 and 9-15, drawn to a method of treating a cardiovascular disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

II. Claims 1, 2, 4 and 9-15, drawn to a method of treating a gastric motility disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

III. Claims 1, 2, 5 and 9-15, drawn to a method of treating urinary incontinence, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

IV. Claims 1, 2, 6 and 9-15, drawn to a method of treating nicotine addiction, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

V. Claims 1, 2, 7 and 9-15, drawn to a method of treating a mood disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

VI. Claims 1, 2 and 8-15, drawn to a method of treating small cell lung carcinoma, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 3, classified in class 514, subclass 13.

VII. Claims 1-3 and 9-11, drawn to a method of treating a cardiovascular disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

VIII. Claims 1, 2, 4 and 9-11, drawn to a method of treating a gastric motility disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

IX. Claims 1, 2, 5 and 9-11, drawn to a method of treating urinary incontinence, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

X. Claims 1, 2, 6 and 9-11, drawn to a method of treating nicotine addiction, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

XI. Claims 1, 2, 7 and 9-11, drawn to a method of treating a mood disorder, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

XII. Claims 1, 2 and 8-11, drawn to a method of treating small cell lung carcinoma, comprising administering a therapeutically effective amount of SEQ ID NO: 1 or 6, classified in class 514, subclass 13.

XIII. Claims 12-15, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of SEQ ID NO: 11, classified in class 514, subclass 13.

XIV. Claims 12-15, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of SEQ ID NO: 4, classified in class 514, subclass 13.

XV. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 5, classified in class 514, subclass 13.

XVI. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a

therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 7, classified in class 514, subclass 14.

XVII. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 8, classified in class 514, subclass 13.

XVIII. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 9, classified in class 514, subclass 13.

XIX. Claims 16-18, drawn to a method of treating a disorder regulated at the level of neuronal nicotinic acetylcholine receptors (nAChR's), comprising administering a therapeutically effective amount of a peptide in which Tyr or iodinated Tyr is added N-terminally to SEQ ID NO: 12, classified in class 514, subclass 13.

The inventions are distinct, each from the other because of the following reasons.

Inventions I – XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of groups I-VI is drawn to a method of treating a different disease, and each of groups VII-XII is drawn to a method of treating a different disease. Where two groups in the set of groups I-XII are drawn to a method of treating the same disease, different therapeutic compounds are administered. Groups XIII-XIX are drawn to methods of treating a genus of diseases, but in each method, a different therapeutic compound is administered. All of therapeutic compounds in groups XIII-

XIX are different from all of the therapeutic compounds in Groups I-XII. Therefore, all of these inventions are patentably distinct.

Claim 1 link(s) the inventions of groups I – VI and the inventions of groups VII – XII, and it will be examined if one of groups I – XII is elected. But, each of these inventions is a separate and distinct method for the reasons discussed above. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and

specification for compliance with the statutes concerning new matter, distinctness, written description and enablement.

As discussed above, Applicants must choose **ONE** polypeptide from among those claimed as indicated in the different groups above. Each polypeptide sequence is a distinct invention requiring separate searches. These are NOT species. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, each of these polypeptides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-06-27

Rosanne Kosson

JON WEBER
SUPERVISORY PATENT EXAMINER